



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0334; FRL-9983-29]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone in or on multiple commodities which are identified and discussed later in this document. In addition, the established pyroxasulfone tolerance on cotton, undelinted seed is removed. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0334, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0334 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0334, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 23, 2017 (82 FR 49020) (FRL-9967-37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 7E8570 & 7E8585) by IR-4 Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.659 be amended as follows:

a. Amend 180.659(a)(1), by establishing a tolerance for residues of the herbicide pyroxasulfone, including its metabolites and degradates, determined by measuring only the sum of pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1 H-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolite, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1 H-pyrazol-4-carboxylic acid (M-3), calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity: Cottonseed subgroup 20C at 0.04 parts per million (ppm). In addition, the petitioner requested removal of the established tolerance on Cotton, undelinted seed at 0.04 ppm (PP 7E8585).

b. Amend 180.659(a)(5) by establishing a tolerance for residues of the herbicide pyroxasulfone, including its metabolites and degradates, determined by measuring only the sum of pyroxasulfone, (3-[(5-difluoromethoxy-1-methyl-3-(trifluoromethyl)pyrazol-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole), and its metabolites, M-1 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl) methanesulfonic acid), M-3 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid), M-25 (5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid) and M-28 (3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid) calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodities: Peppermint, oil at 0.48 ppm; peppermint, tops at 0.15 ppm; spearmint, oil at 0.48 ppm; spearmint, tops at 0.15 ppm; soybean, vegetable, succulent at 0.2 ppm (PP 7E8570); and Leaf petiole vegetable subgroup 22B at 0.3 ppm (PP 7E8585).

c. Amend 180.659(c) Tolerances with regional registrations, by establishing a tolerance for residues of the herbicide pyroxasulfone, including its metabolites and degradates,

determined by measuring only the sum of pyrooxasulfone, (3-[(5-difluoromethoxy-1-methyl-3-(trifluoromethyl)pyrazol-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole), and its metabolites, M-1 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl) methanesulfonic acid), M-3 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid), M-25 (5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid) and M-28 (3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid) calculated as the stoichiometric equivalent of pyrooxasulfone, in or on the commodities: Grass, forage at 0.5 ppm and grass, hay at 1.0 ppm (PP 7E8570).

These documents referenced a summary of each petition prepared by K-1 Chemical, USA Inc., the registrant, that are available in the docket, <http://www.regulations.gov>.

One comment was received on the notice of filings. EPA's response to the comment is discussed in Unit IV.C.

Consistent with the authority in FFDCA 408(d)(4)(A)(i), EPA is issuing tolerances that vary from what the petitioner sought. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyrooxasulfone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrooxasulfone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database for pyrooxasulfone is adequate for evaluating and characterizing toxicity and selecting endpoints for purposes of this risk assessment. Pyrooxasulfone acute toxicity to mammals is low by all routes of exposure. Subchronic

and chronic oral studies in mice, rats and dogs produced a variety of effects including cardiac toxicity (increased cardiomyopathy), liver toxicity (centrilobular hepatocellular hypertrophy, histopathological and/or clinical pathological indicators), kidney toxicity (nephropathy), neurotoxicity (impaired hind limb function, ataxia, tremors, sciatic nerve lesions, axonal/myelin degeneration in the sciatic nerve and spinal cord sections), skeletal muscle myopathy, urinary bladder mucosal hyperplasia, and urinary bladder transitional cell papillomas. Dogs appear to be the most sensitive species in regard to neurotoxic effects of pyroxasulfone via the oral route. Cardiac toxicity (myofiber degeneration and local inflammation) were also seen in a rat dermal toxicity study. Pyroxasulfone did not elicit immunotoxic effects in rats or mice. Neurotoxicity was seen in a developmental neurotoxicity study in offspring rats (decreased brain weight, decreased thickness of the hippocampus, corpus callosum and cerebellum). There is evidence of fetal and offspring quantitative susceptibility in the developmental neurotoxicity study in rats as effects occurred in the absence of maternal toxicity. There is no concern for reproductive toxicity.

Pyroxasulfone is classified as “Not Likely to be Carcinogenic to Humans” at doses that do not cause crystals with subsequent calculi formation resulting in cellular damage of the urinary tract. The Agency has determined that the quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyroxasulfone.

Specific information on the studies received and the nature of the adverse effects caused by pyroxasulfone as well as the no-observed-adverse-effect-level (NOAEL) and

the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled, “**SUBJECT: Pyroxasulfone** Human Health Risk Assessment for the Section 3 New Uses of Pyroxasulfone on Mint, Edamame (vegetable soybean), Grass (seed crop) for the Pacific Northwest only, Leaf Petiole Vegetable Subgroup 22B and Expansion of Cottonseed Subgroup 20C,” at pages 34-79 in docket ID number EPA-HQ-OPP-2017-0334.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for pyrozasulfone used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of May 17, 2018 (83 FR 22854) (FRL-9977-25).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrozasulfone, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrozasulfone tolerances in 40 CFR 180.659. EPA assessed dietary exposures from pyrozasulfone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for pyrozasulfone. In estimating acute dietary exposure, EPA used 2003-2008 food consumption data from the United States Department of Agriculture's (USDA) National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues adjusted for metabolites that are not in the tolerance expression, except for soybean and subgroup 22B commodities, for which EPA used anticipated residues from field trial data.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance level residues that were

adjusted for metabolites not in the tolerance expression, except for soybean and subgroup 22B commodities, for which EPA used anticipated residues from field trial data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pyroxasulfone. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment for pyroxasulfone; 100% CT was assumed for all food commodities. Tolerance-level residues were used for all commodities except soybean and subgroup 22B commodities, for which EPA used anticipated residues from field trial data.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyroxasulfone

in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrozasulfone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of pyrozasulfone for acute exposures are estimated to be 16.7 parts per billion (ppb) for surface water and 210 ppb for ground water. EDWCs of pyrozasulfone for chronic exposures for non-cancer assessments are estimated to be 4.5 ppb for surface water and 174 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 210 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 174 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyrozasulfone is not registered for any specific use patterns that would result in residential exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found pyrooxasulfone to share a common mechanism of toxicity with any other substances, and pyrooxasulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrooxasulfone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is

commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Pyroxasulfone did not exhibit developmental toxicity in the rat guideline study at the limit dose of 1,000 mg/kg/day and it exhibited slight developmental toxicity in rabbits (reduced fetal weight and resorptions) at the limit dose of 1,000 mg/kg/day. However, developmental effects (decreased brain weight and morphometric changes) were noted in offspring at 300 mg/kg/day in the rat developmental neurotoxicity (DNT) study compared to no maternal toxicity at 900 mg/kg/day. In a reproductive toxicity in rats, reduced pup weight and body weight gains during lactation occurred at similar or higher doses causing pronounced maternal toxicity (reduced body weight, body weight gain and food consumption and increased kidney weight, cardiomyopathy and urinary bladder mucosal hyperplasia with inflammation).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for pyroxasulfone is complete.
- ii. The neurotoxicity database, including acute, subchronic and chronic studies, shows adverse effects from pyroxasulfone exposure in mice, rats and dogs, with the latter species showing greatest sensitivity. Although the DNT study indicated offspring are more sensitive to neurotoxic effects of pyroxasulfone, the dose-response is well

characterized for neurotoxicity and a NOAEL is identified; therefore, there is no residual uncertainty with regard to neurotoxic effects for which a 10X must be retained.

iii. As noted in Unit III.D.2., the available database shows evidence of increased susceptibility of fetuses and offspring in a DNT study in rats and in a developmental study in rabbits following *in utero* or post-natal exposure to pyroxasulfone. The Agency concludes, however, that there is no residual uncertainty concerning these effects. The available studies show clear NOAELs and LOAELs for these effects, which are occurring only at doses much higher than the endpoints on which the Agency is regulating.

iv. There are no residual uncertainties in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or residues based on field trials. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyroxasulfone in drinking water. These assessments will not underestimate the exposure and risks posed by pyroxasulfone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure analysis, the risk estimate for acute dietary exposure from food and water to pyrooxasulfone is at 3.7% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure. The acute dietary risk is not of concern (<100% aPAD).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure analysis, EPA has concluded that risk estimates for chronic exposure to pyrooxasulfone from food and water are not of concern (<100% cPAD) with a risk estimate at 50% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for pyrooxasulfone.

3. *Short-and intermediate term risk.* Short- and intermediate-term adverse effects were identified; however, pyrooxasulfone is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for pyrooxasulfone.

4. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., the Agency has determined that the quantification of risk using a non-linear (*i.e.*, RfD)

approach will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyrooxasulfone. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., pyrooxasulfone is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyrooxasulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography/triple quadrupole mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for residues of pyrooxasulfone in or on any of the petitioned-for commodities associated with this regulatory action.

C. Response to Comments

One anonymous public comment was received that expressed concerns about the cost of EPA regulations to tax payers and corporations. This comment did not raise any issue relevant to the Agency's safety determination for this tolerance action. Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) allows EPA to set tolerances for residues of pesticide chemicals when it determines that the tolerance meets the safety standard imposed by that statute. EPA has made that determination for the pyrooxasulfone tolerances established by this final rule.

D. Revisions to Petitioned-For Tolerances

EPA calculated tolerance levels using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures, available field trial residue data, and metabolite concentrations covered to parent equivalents. The Agency is also harmonizing with relevant Canadian MRLs. In addition, the Agency is using commodity terminology consistent with the terms generally used for tolerances.

As a result, the Agency is establishing tolerances that differ from the petitioned-for tolerances as follows: 1) The proposed pyroxasulfone tolerances on both Peppermint, oil and Spearmint, oil at 0.48 ppm are being established at 0.70 ppm; 2) the proposed pyroxasulfone tolerances on both Peppermint, fresh leaves and Spearmint, fresh leaves at 0.15 ppm are being each established at 0.20 ppm; and 3) the proposed tolerance on Leaf petiole vegetable subgroup 22B at 0.3 ppm is being established at 0.80 ppm.

In addition, although the petitioner requested a tolerance on Soybean, vegetable, succulent at 0.2 ppm, this term is broad and covers two forms of vegetable soybean—Soybean, vegetable, succulent shelled, and Vegetable, soybean, edible podded; therefore, to conform to the Agency's commodity terminology for soybeans, the Agency is establishing the tolerance requested as separate tolerances at 0.40 ppm for both forms of succulent soybean vegetable.

V. Conclusion

Therefore, tolerances are established for residues of pyroxasulfone, including its metabolites and degradates, in or on Cottonseed subgroup 20C at 0.04 ppm; Leaf petiole vegetable subgroup 22B at 0.80 ppm; Peppermint, fresh leaves at 0.20 ppm; Peppermint, oil at 0.70 ppm; Soybean, vegetable, succulent shelled at 0.40 ppm; Spearmint, fresh leaves at 0.20 ppm; Spearmint, oil at 0.70 ppm; and Vegetable, soybean, edible podded at 0.40 ppm. In addition, tolerances with regional registrations are established in or on Grass, forage at 0.50 ppm and Grass, hay 1.0 ppm. Lastly, the Agency is removing the existing pyroxasulfone tolerance on Cotton, undelinted seed that is superseded by this final rule.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 9, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.659:

a. In the table in paragraph (a)(1):

i. Remove the entry “Cotton, undelinted seed”;

ii. Add alphabetically the commodity, ”Cottonseed subgroup 20C”;

b. In the table in paragraph (a)(5), add alphabetically the commodities, “Leaf petiole vegetable subgroup 22B”; “Peppermint, fresh leaves”; “Peppermint, oil”; ”Soybean, vegetable, succulent shelled”; “Spearment fresh leaves”; “Spearment, oil”; and “Vegetable, soybean, edible podded”; and

c. Revise paragraph (c).

The additions and revisions read as follows:

§ 180.659 Pyroxasulfone; tolerances for residues.

(a) * * * (1) * * *

| Commodity | Parts per million |
|-----------|-------------------|
|-----------|-------------------|

| | |
|--------------------------|-------|
| * * * * | * * * |
| Cottonseed, subgroup 20C | 0.04 |
| * * * * | * * * |

* * * * *

(5) * * *

| Commodity | Parts per million |
|---------------------------------------|-------------------|
| * * * * | * * * |
| Leaf petiole vegetable subgroup 22B | 0.80 |
| * * * * | * * * |
| Peppermint, fresh leaves | 0.20 |
| Peppermint, oil | 0.70 |
| * * * * | * * * |
| Soybean, vegetable, succulent shelled | 0.40 |
| Spearmint, fresh leaves | 0.20 |
| Spearmint, oil | 0.70 |
| * * * * | * * * |
| Vegetable, soybean, edible podded | 0.40 |
| * * * * | * * * |

* * * * *

(c) *Tolerance with regional registrations.* Tolerances are established for residues of the herbicide pyroxasulfone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyroxasulfone (3-[(5-difluoromethoxy-1-methyl-3-(trifluoromethyl)pyrazol-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole), and its metabolites, M-1 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid), M-3 (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid), M-25 (5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid) and M-28 (3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid) calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity.

| Commodity | Parts per million |
|---------------|-------------------|
| Grass, forage | 0.50 |
| Grass, hay | 1.0 |

* * * * *